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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,569	08/13/2002	Robert C. Brunham	1038-1226 MIS:jb	4846

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,569	BRUNHAM, ROBERT C.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,17,18 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,17,18,21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant filed a response to the Non-Final Action of October 27, 2005 on April 26, 2006. Claims 1-11, 13-16, 19, 20 are cancelled. Claims 12, 13 are amended.

Claims 12, 17, 18, 21-23 are under consideration.

Withdrawn Rejection

35 U.S.C § 112, 1st parag., Written Description

Applicant's arguments, see page 4 of Applicant's response, filed April 26, 2006, with respect to the rejection of claims 12, 17, 18, 21-23 under 35 U.S.C. 112, 1st parag., Written Description, have been fully considered and are persuasive. Applicant has amended the claims to SEQ ID NO. 1. The rejection of claims 12, 17, 18, 21-23 has been withdrawn. It is noted that the rejection of claims 13-16, 19, 20 is withdrawn as the claims have been cancelled.

New/Maintained Rejection

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 23 is newly rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,632,663 B1 ('663). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of '663 is drawn to a specific promoter: human cytomegalovirus major intermediate-early promoter-enhancer region. Claim 23 is more generally drawn to a cytomegalovirus promoter. As such, the '663 claim is a species of the instant claim. It is well established that a species of a claimed invention renders the genus obvious. *In re Schaumann* , 572 F.2d 312, 197 USPQ 5 (CCPA 1978).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22, 23 remain rejected in modified form under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

1. a method of producing a vaccine for protection of a host against disease caused by infection with Chlamydia trachomatis MoPn EB, comprising administering pcDNA plasmid construct comprising SEQ ID NO. 1 operably linked to at least one control sequence that directs expression of a protein encoded by SEQ ID NO. 1 in a mouse, wherein said plasmid construct is administered intramuscularly and intranasally at 0, 2, and 4 weeks, and wherein following intranasal challenge of C. trachomatis MoPn EB, the mouse exhibits a reduction of C. trachomatis MoPn titer in the lungs

does not reasonably provide enablement for

1. a method of producing a vaccine for protection of any host against disease caused by infection with any strain of Chlamydia, which comprises:

isolating a nucleotide sequence of SEQ ID NO. 1,

operably linking said nucleotide sequence to at least one control sequence to produce a plasmid vector, wherein the control sequence directs expression of SEQ ID NO. 1, when introduced to any host, other than mouse, to produce any immune response to the protein encoded by SEQ ID NO. 1, and

formulating said vector as a vaccine for in vivo administration to any host, other than mouse,

and

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for reasons of record, December 27, 2005.

Response to Arguments

Applicant's arguments, see page 4 of Applicant's response, filed April 26, 2006, with respect to the rejection of claims 12, 17, 18, 21-23 have been fully considered and are persuasive in part.

With regard to the issue that the claims were drawn to any serine-threonine kinase (STK) of any strain of Chlamydia or to a fragment of STK, Applicant has amended the claims to only SEQ ID NO. 1. This amendment is found to be persuasive. With regard to this issue, the rejection, as it applies to claims 12, 17, 18, 21-23 is withdrawn. It is noted that the rejection of claims 13-16, 19, 20 is withdrawn as the claims have been cancelled.

With regard to the issue that the claims were readable on any non-replicating vector, which encompassed viral vectors, Applicant amended the claims to encompass plasmids. The amendment is found to be persuasive. With regard to this issue, the rejection, as it applies to claims 12, 17, 18, 21-23 is withdrawn. It is noted that the rejection of claims 13-16, 19, 20 is withdrawn as the claims have been cancelled.

With regard to the issue that the claims were readable on any route of delivery for the DNA construct, Applicant amended the claims to encompass intranasally and intramuscularly. The amendment is found to be persuasive. With regard to this issue,

the rejection, as it applies to claims 12, 17, 18, 21-23 is withdrawn. It is noted that the rejection of claims 13-16, 19, 20 is withdrawn as the claims have been cancelled.

With regard to the claims being drawn to a method of making a vaccine for any host, upon further consideration, the Examiner finds the scope enabling for any host.

As such, Applicant has overcome these issues as they apply to claims 12, 17, 18, 21-23.

However, with regard to the claims being drawn to a method of making a vaccine for any strain of Chlamydia using a plasmid comprising SEQ ID NO. 1, the Examiner has indicated (Office Action, page 9) that because there if significant variation between the nucleotide sequences of different strains and species of Chlamydia, an artisan could not reasonably predict that a protein encoded by SEQ ID NO. 1 could be used to generate antibodies against other species and strains of Chlamydia (in particular, see claim 22). While the specification teaches Chlamydia trachomatis MoPn EB obtained from SEQ ID NO. 1, the specification does not teach immunization, using SEQ ID NO. 1 has an effect on other strains of Chalmydia. As such, this issue of rejection remains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 17, 18, 21 are newly rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 uses the phrase, "gene encoding a serine-threonine kinase." However, a "gene," in addition to the coding region, also encompasses a regulatory region. It is unclear how SEQ ID NO. 1, which is a nucleic acid sequence encoding a protein is the same as a "gene." Changing "gene" to "nucleic acid" would be remedial.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER